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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,672	02/06/2006	Takashi Kobayashi	272405US0PCT	7664
22850	7590	02/21/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER RAHMANI, NILOOFAR	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 02/21/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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oblonpat@oblon.com
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Office Action Summary

Application No.

10/535,672

Applicant(s)

KOBAYASHI, TAKASHI

Examiner

Niloofar Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. Claims 1-5 are currently pending in the instant application.

Priority

2. This application is file on 02/06/2006, which is a 371 of PCT/JP03/12898, filed on 10/08/2003, which claims priority of JAPAN 2002-336867, filed on 11/20/2002, and JAPAN 2003-136738, FILED ON 05/15/2003, and JAPAN 2003-286386, filed on 05/08/2003.

3. *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are rejected because the term " derivative" is vague and unclear. Does it mean further derivative of formula (1)? How much of derivative is being claimed.

The word "derivative" is indefinite for we do not know which compounds are contemplated. A derivative is the result of a reaction upon an organic molecule. Since we do not know the reagents or the conditions of these reactions, there is no way of determining the structures of the claimed "derivatives". The phrase "derivative" is, in essence, a product by process claim. Yet Applicants have not described the intended processes sufficiently that we

may understand the structures of the compounds they claim. Webster's New World Dictionary defines derivative as "a substance derived from ... another substance by chemical change", and "substitution of one or more elements or radicals for one or more constituents of the original substance" has occurred. All implying that new chemical bonds have formed.

4. Claims 1-5 are rejected because the formula (1) is vague and indefinite. There is no structure for formula (1). What the formula (1) is? Correction is required.

5. Claims 1-5 are rejected because of the term "a drug". Are they claiming "a compound" or "pharmaceutical composition" or "method for treating"? Correction is required.

6. Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not describe in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification lacks written description of the claim i.e. "derivative". No information

was found in the specification that any and all known reactive derivatives can be used for the process.

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being possibly enabling for treating specific diseases, does not reasonably provide enablement for preventing diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants are not enabled for preventing any of these diseases. The only established prophylactics are vaccines not the compounds such as present here. In addition, it is presumed that "prevention" of the claimed diseases would require a method of identifying those individuals who will develop the claimed diseases before they exhibit symptoms. There is no evidence of record that would guide the skilled clinician to identify those who have the potential of becoming afflicted.

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art, and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. 1) As discussed above, preventing diseases requires identifying those patients who will acquire the disease before occurs.

This would require extensive and potentially opened ended clinical research on healthy subjects. 2) The passage spanning line 6-17, page 4 lists the diseases Applicant intend to treat. 3) There is no working example of such a preventive procedure in man or animal in the specification. 4) The claims rejected are drawn to medical treatment and are therefore physiological in nature. 5) The state of the art is that no general procedure is art-recognized for determining which patients generally will become afflicted before the fact. 6) The artisan using Applicants invention would be a Board Certified physician in *** diseases with an MD degree and several years of experience. Despite intensive efforts, pharmaceutical science has been unable to find a way of getting a compound to be effective for the prevention of diseases generally. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs. Novo Nordisk*, 42 USPQ2nd 1001, 1006. This establishes that it is not reasonable to any agent to be able to prevent diseases generally. That is, the skill is so low that no compound effective generally against diseases has ever been found let alone one that can prevent such conditions. 7) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). 8) The claims broadly read on all patients, not just those undergoing therapy for the claimed diseases and on the multitude of compounds embraced by Formula (1).

The Examiner suggests deletion of the word "prevention".

8. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

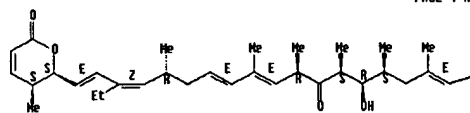
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuhnt et al., *Applied and Environmental Microbiology*, 1998, 64(2), pages 714-720. Kuhnt et al. disclosed the instant claimed compound

RN 87081-35-4

CN 2,10,12,16,18-Nonadecapentaenoic acid, 19-[(2S,3S)-3,6-dihydro-3-methyl-6-oxo-2H-pyran-2-yl]-17-ethyl-6-hydroxy-3,5,7,9,11,15-hexamethyl-8-oxo-, (2E,5S,6R,7S,9R,10E,12E,15R,16Z,18E)-



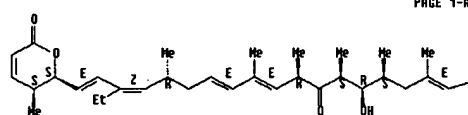
CO₂H

which known as antifungal and antitumor and exhibits significant antiproliferative activity. Therefore, the instant claim is anticipated by Kuhnt et al.

9. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al., Traffic (Copenhagen, Denmark), 2001, 2(11), pages 812-819. Lam et al. disclosed the instant claimed compound

RN 87081-35-4

CN 2,10,12,16,18-Nonadecapentaenoic acid, 19-[(2S,3S)-3,6-dihydro-3-methyl-6-oxo-2H-pyran-2-yl]-17-ethyl-6-hydroxy-3,5,7,9,11,15-hexamethyl-8-oxo-, (2E,5S,6R,7S,9R,10E,12E,15R,16Z,18E)-



PAGE 1-B

CO₂H

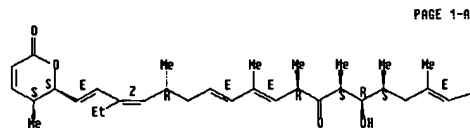
which known as antitumor and exhibits significant antiproliferative activity.

Therefore, the instant claim is anticipated by Lam et al.

10. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Meng et al., Journal of Biological Chemistry, 2001, 276(43), pages 40113-40119. Meng et al. disclosed the instant claimed compound

RN 87081-35-4

CN 2,10,12,16,18-Nonadecapentaenoic acid, 19-[(2S,3S)-3,6-dihydro-3-methyl-6-oxo-2H-pyran-2-yl]-17-ethyl-6-hydroxy-3,5,7,9,11,15-hexamethyl-8-oxo-, (2E,5S,6R,7S,9R,10E,12E,15R,16Z,18E)-



PAGE 1-B

CO₂H

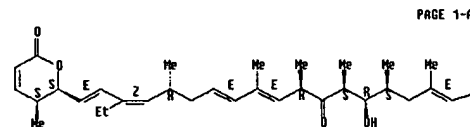
which known as antitumor and exhibits significant antiproliferative activity.

Therefore, the instant claim is anticipated by Meng et al.

11. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Neufeld et al., Proceedings of the National Academy of Sciences of the United States of America (2000), 97(22),pages 12085-12090. Neufeld et al. disclosed the instant claimed compound

RN 87081-35-4

CN 2,10,12,16,18-Nonadecapentaenoic acid, 19-[(2S,3S)-3,6-dihydro-3-methyl-6-oxo-2H-pyran-2-yl]-17-ethyl-6-hydroxy-3,5,7,9,11,15-hexamethyl-8-oxo-, (2E,5S,6R,7S,9R,10E,12E,15R,16Z,18E)-



PAGE 1-B

CO₂H

which known as antitumor and exhibits significant antiproliferative activity.

Therefore, the instant claim is anticipated by Neufeld et al.

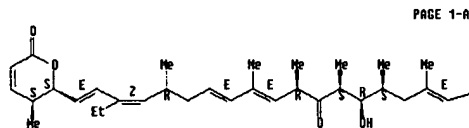
12. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hietanen et al., Proceedings of the National Academy of Sciences

of the United States of America (2000), 97(15), pages 8501-8506. Hietanen et al.

disclosed the instant claimed compound

RN 87081-35-4

CN 2,10,12,16,18-Nonadecapentaenoic acid, 19-[(2S,3S)-3,6-dihydro-3-methyl-6-oxo-2H-pyran-2-yl]-17-ethyl-6-hydroxy-3,5,7,9,11,15-hexamethyl-8-oxo-, (2E,5S,6R,7S,9R,10E,12E,15R,16Z,18E)-



CO₂H

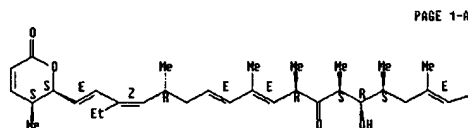
which known as antitumor and exhibits significant antiproliferative activity.

Therefore, the instant claim is anticipated by Hietanen et al.

13. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Smart et al., *Oncogene*, 1999, 18(51), pages 7378-7386. Smart et al. disclosed the instant claimed compound

RN 87081-35-4

CN 2,10,12,16,18-Nonadecapentaenoic acid, 19-[(2S,3S)-3,6-dihydro-3-methyl-6-oxo-2H-pyran-2-yl]-17-ethyl-6-hydroxy-3,5,7,9,11,15-hexamethyl-8-oxo-, (2E,5S,6R,7S,9R,10E,12E,15R,16Z,18E)-



PAGE 1-B

CO₂H

which known as antitumor and exhibits significant antiproliferative activity.

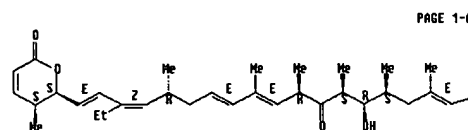
Therefore, the instant claim is anticipated by Smart et al.

14. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Komiyama et al., Journal of Antibiotics, 1985, 38(3), pages 427-9.

Komiyama et al. disclosed the instant claimed compound

RN 87081-35-4

CN 2,10,12,16,18-Nonadecapentaenoic acid, 19-[(2S,3S)-3,6-dihydro-3-methyl-6-oxo-2H-pyran-2-yl]-17-ethyl-6-hydroxy-3,5,7,9,11,15-hexamethyl-8-oxo-, (2E,5S,6R,7S,9R,10E,12E,15R,16Z,18E)-



PAGE 1-B

CO₂H

which known as antitumor and exhibits significant antiproliferative activity.

Therefore, the instant claim is anticipated by Komiyama et al.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is

571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI


MARGARET D. SEAMAN

02/05/2008



PRIMARY EXAMINER

GROUP 1625